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09/997,588	11/29/2001	Chen Xing Su	10209.353	6233

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KIRTON AND MCCONKIE
1800 EAGLE GATE TOWER
60 EAST SOUTH TEMPLE
P O BOX 45120
SALT LAKE CITY, UT 84145-0120

EXAMINER

PATTEN, PATRICIA A

ART UNIT

PAPER NUMBER

1654

DATE MAILED: 12/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/997,588

Applicant(s)

SU ET AL.

Examiner

Patricia A Patten

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 4-28 is/are pending in the application.
- 4a) Of the above claim(s) 13-23,27 and 28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1,4-12 and 24-26 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other: ____.

DETAILED ACTION

Claims 1 and 4-28 are pending in the application.

Claims 13-23 were withdrawn from further consideration on the merits as being drawn to a non-elected invention per the election without traverse in the Office Action dated 6/18/03. Claims 27 and 28 were also withdrawn from consideration as being drawn to a non-elected invention due to election by original presentation in the Office Action dated 2/11/03.

Claims 1, 4-12 and 24-26 were presented for examination on the merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Specification

The use of the trademarks PYCNOGENOL and TAHITIAN NONI has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims are newly rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Specifically, claim 1 recites 'three ounces of a dietary supplement comprising *Morinda citrifolia* fruit juice'. Claim 9 newly recites 'consuming three ounces of a liquid composition comprising processed *Morinda citrifolia*'. It cannot be found, in the Instant specification as filed, where Applicants have disclosed where three ounces of *Morinda citrifolia* was formulated into a composition or used in a method for treating. Although

Art Unit: 1654

Applicants state 'more than one ounce', this limitation is very broad and does not necessarily include 'three ounces'. It is noted that Applicants did not provide for any clear definition of the term 'more than one ounce'. Therefore, because it cannot be absolutely determined if Applicants contemplated 'three ounces of *Morinda citrifolia*' it is deemed that Applicants were not in possession of the claimed invention at the time the Instant disclosure was filed.

Also, the newly recited phrase 'elevated equipment' in Claim 1 is considered New Matter. The Instant specification recites where "The fruit is allowed to ripen or age from 0 to 14 days by being placed on equipment so that the ripening fruit is prevented from contacting the ground" (p.11 Instant specification) however, does not teach wherein the equipment is 'elevated'. Elevation of the equipment is not necessarily the only means for placing the fruit on equipment to prevent it from touching the ground. For example, the equipment could be underground; i.e., a bucket in a hole in the ground containing the fruit. Thus, the fruit would not be 'elevated' and the fruit would not touch the ground. Therefore, it does not appear that Applicants contemplated this particular concept at the time of filing the Instant specification. Thus, 'elevated equipment' is considered New Matter.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 7 and 25 are newly rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 7 and 25 all add an 'additional ingredient' to the *Morinda citrifolia* juice. However, each independent claim clearly stated that the *Morinda citrifolia* juice was present in the composition between about 10 and about 100 percent of the composition. It is not understood how an additional ingredient could be added into the composition when the *Morinda citrifolia* may take up the entire 100% of the composition and therefore these claims are indefinite.

Claim 1 recites 'elevated'. This term is indefinite because the Examiner cannot ascertain exactly what Applicants mean by this term. Does elevated mean elevated from the ground or elevated from some other point in space? The ordinary artisan would have trouble determining what Applicants intend for this term to mean, and thus, the term is indefinite.

Correction is necessary.

Claim Rejections - 35 USC § 103

Claims 1, 4-12, 24 and 26 are newly rejected under 35 U.S.C. 103(a) as being unpatentable over Mumford (1998) in view of Brock et al. (1991), in view of Gagnon (1997) and further in view of Nahir (EP 0 555 573 A1).

Applicants' arguments were fully considered, but not found persuasive.

The Examiner will reiterate the previous reasoning for the rejections Mumford (1998) in view of Brock et al. (1991) and in view of Gagnon (1997) :

Mumford (1998) reported that noni juice (a.k.a. *Morinda citrifolia*) was well known and marketed as a nutritional/medicinal product (p.1). Mumford specifically reported that Keren Swift began taking two ounces of noni juice per day after she noticed a change in migraine headaches (p.1). Because the article taught 'noni juice' and because the article did not specifically mention that the juice had been 'dried or powdered', it is deemed that the 'juice' to which the article is referring is the liquid squeezed from the *M.citrifolia* fruit, especially absent sufficient evidence to the contrary. It is further deemed that because the article recited 'juice' that the juice was 100% *M.citrifolia* juice.

Mumford (1998) did not specifically teach wherein the *M.citrifolia* juice was pasteurized, where the juice was taken on an empty stomach, the addition of sweeteners or carriers to the juice, or the new limitations to the claims which include:

1. Wherein three ounces of *M.citrifolia* is administered,
2. Wherein the fruit is placed on elevated equipment and allowed to ripen from 0-14 days (it is noted that it is the 'elevation' which is a new limitation; 'ripening' was present in claim 6 for example and previously rejected),
3. Wherein the pulp is filtered from the juice via filtering equipment, and
4. Wherein the dietary supplement is pasteurized at a minimum temperature of 180 ° F.

Milk and juices are routinely pasteurized in order to reduce the amount of bacterial contaminants as well as preserve the beverages for longer amounts of time according to Brock et al. (1991). Specifically, Brock et al. taught that pasteurization was found applicable to 'wine, beer, cider, vinegar, milk, and countless other perishable beverages, foods and organic products' (p.334).

Gagnon (1997) suggested '...taking extracts between meals, apart from food, because that is when they are more easily absorbed by the body. This way ,extracts enter the bloodstream readily and immediately start the healing process' (p.27).

Mechanical separation of seeds, peel and pulp from fruit juice was well known, conventional practice in the art at the time the Invention was made: Nahir (EP 0 555 573 A1) disclosed an apparatus for making juice which removed the pulp, peel and seeds from fruit to obtain pulp-free fruit juice (Fig. 1 and p.4, lines 20-56):

Art Unit: 1654

"The described movement of the pusher 24 along the axis 40 causes each back flap 31 to engage and thus push a fruit from a corresponding transport location 18 of the feed conveyor to a corresponding pulp removal location. At the same time, front flap 30 is operative to engage an empty fruit peel, from which the pulp has been removed and which is located on one of the doors 20, and to push the fruit peel into a waste conveyor 47" (p.4, lines 24-28).

Further:

"Therefore, as the juice sacs falling into the trough are carried towards the lower end thereof, any fruit seeds that may be present in the flow float to the top and are discharged to a seed reception member 52" (p.4, lines 41-42)

One of ordinary skill in the art would have been motivated to pasteurize the noni juice as disclosed by Mumford (1998) in order to have prolonged the shelf life of the juice. Brock et al. made it clear that pasteurization of beverages was common, routine practice in the art of beverage making, and well within the purview of the ordinary artisan. Although Brock did not specifically teach wherein the liquids were pasteurized at a minimum of 180 ° F, it is deemed that the ordinary artisan would have had a reasonable expectation that pasteurization at this temperature would have provided enough heat to kill microorganisms present in the juice. As related in the previous Office action, One of ordinary skill in the art would have been motivated to pasteurize the noni juice in order to have prolonged the shelf life of the juice. Brock et al. made it clear that pasteurization of beverages was common, routine practice in the art of beverage making, and well within the purview of the ordinary artisan.

The ordinary artisan would have been motivated to ingest the noni juice on an empty stomach in order to have allowed the juice to be absorbed by the body more readily, thereby obtaining the maximum medicinal benefit of the juice.

One of ordinary skill in the art would have been motivated to have added carriers and sweeteners (whereby a carrier and a sweetener are respectively deemed 'at least one other ingredient') to noni juice in order to have formulated noni juice compositions containing varying percentages of active ingredients (i.e., 'regular' -vs- 'extra strength') as well as for mere ease of delivery. It was routine in the art of pharmacology to admix active ingredients with carriers, colorings and sweeteners for example. Carriers were an advantageous means of diluting active ingredients to necessary dosage ranges. Further, sweeteners and colorings would not have changed the medicinal qualities of the noni.

The language 'inhibiting, preventing and reversing cell membrane disruption' is merely an intrinsic property of the method which would have naturally manifested as a result of drinking the juice.

As stated in the previous Office Action, although the reference does not teach wherein the noni fruit is harvested when it is at least one inch long and twelve inches in diameter, the Examiner deems that the fruit, containing intrinsic phytochemicals, would

have contained these phytochemicals (active ingredients) during the growing stages of the fruit. The Examiner cannot find any evidence within the Instant specification which clearly indicates that the harvesting limitations found in the claims materially change the characteristics of noni. Thus, it is deemed that the method for harvesting *does not change the method* since the juice is substantially the same juice as described by Mumford especially lacking clear, credible evidence to the contrary.

Further, harvesting limitations such as separating spoiled fruit, and placing the harvested fruit in a plastic container, does not materially change the method for scavenging lipid hydroperoxides. Applicants are *merely reciting pre-operative steps* which do not change the method for reducing cellular damage.

It is further noted that the ordinary artisan would have recognized that *M.citrifolia* juice, and *M.citrifolia* juice which had come from a concentrate (i.e., reconstituted) would have been substantially the same product. It is deemed that a 'reconstituted' *M.citrifolia* juice, and a crude *M.citrifolia* juice would not be distinguishable from each other since concentration and 'reconstitution' are merely the subtraction and addition of water. Therefore, claim 12 which states that the method includes *M.citrifolia* juice which was obtained 'without drying or powdering' combined with *M.citrifolia* juice which was reconstituted would not have materially changed the composition nor the medicinal effects of the *M.citrifolia* juice.

One of ordinary skill in the art would have been motivated to ingest 3 ounces of noni juice in order to obtain increased medicinal effects from the known medicinally active noni juice. Although none of the references specifically taught wherein three ounces of *M.citrifolia* was administered, it was clear from Mumford (1998) that *M.citrifolia* juice was taken by people for medicinal purposes. Variations in dosing regimens of products with known medicinal qualities was routine in the art. Such variations were considered optimization of result effective variables. In the Instant case, because noni juice was known for its medicinal properties, the ordinary artisan would have had a reasonable expectation that ingestion of three ounces of noni juice per day would have had an additive medicinal. It is further noted that the Instant specification does not delineate the effects of drinking particular amounts of noni juice, as the Instant specification simply teaches that 'more than one' or 'less than one' ounce of noni juice may be administered to produce beneficial effects.

One of ordinary skill in the art would have been motivated to remove the pulp from the noni juice in order to provide the consumer with a choice of juice with pulp or pulp free. Further, one of ordinary skill in the art would have been motivated to filter the pulp away from the juice because filtration of the pulp would have ensured good removal of the pulp. It was clear from the prior art, as well as conventional knowledge, that juices were/are provided as pulp-containing or pulp-free because consumers have varying likes of taste, and therefore, the ordinary artisan would have had a reasonable expectation that giving the consumer a choice between pulp-containing and pulp-free juice would have been advantageous in marketing the product for individual tastes.

It is reiterated that Specific process for obtaining the juice does not materially change the method. The term 'juice,' as defined by Webster's Dictionary, means 'the liquid part of a plant, fruit, or vegetable.' Thus, it is deemed that the juice disclosed by Mumford was the liquid of the fruit which had been separated from solids such as the seeds and the peel. Applicants have amended the claims to include specific pre-operative processing steps which are conventional in the art of making juice. As stated *supra*, the juice is the liquid part of the fruit. Therefore, the seeds and peel must have been removed from the liquid (juice) portion of the fruit in order to obtain the liquid. Although the references did not particularly teach the manufacturing methods which were employed in making the juice, the ordinary artisan would have had a reasonable expectation that *by some means*, the seeds and the peel were removed; either manually or mechanically. It remains the opinion of the Examiner that the method for obtaining the juice is inconsequential to the patentability of the Instant method claims for the reasons set forth in previous Office Actions as well as for the following reasons:

The Instant claims are methods employing a product made by a particular process (product-by-process):

"[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted).

In the Instant case, although the claims are not product-by-process, they are methods of treating with a product-by-process. The only step for treatment is consumption of three ounces of *Morinda citrifolia* juice. As it was stated in previous office actions, inhibiting, preventing and reversing lipid peroxidation or superoxide anion free radicals would have been an intrinsic characteristic of ingestion of noni juice, especially considering that the only step in the method is consumption of the juice and lacking credible evidence to the contrary. Therefore, it is primarily the *juice* of the Instant claims, and the *juice* of the prior art which has been assessed for differences with regard to patentability, because it was *known* in the art that people *consumed* noni juice.

As stated in previous Office Actions, a difference between the Instantly recited juice, and the juice of the prior art cannot be ascertained. The Instant specification does not teach that the process for making the noni juice had any impact on the medicinal qualities of the juice, nor have Applicants provided any indication that the juice of the Instant claims is materially different from the noni juice of the prior art. Although the prior art references did not specifically teach each aspect of the process for obtaining the noni juice as recited in the Instant claims, it is deemed, absent sufficient evidence to the contrary, that the end product obtained by the product-by-process in the Instant method claims is the same, or so substantially similar to the prior art noni juice that the Examiner cannot determine any difference. Thus, it is deemed that the noni juice which was consumed in the prior art was the same or substantially the same noni juice as Instantly claimed. Because the noni juice was the same or substantially the same, simple consumption of the noni juice would have manifested the intrinsic characteristics as Instantly claimed thereby obviating the claimed invention as indicated by Mumford.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A Patten whose telephone number is (703) 308-1189. The examiner can normally be reached on 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (703) 306-3220. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-3906.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

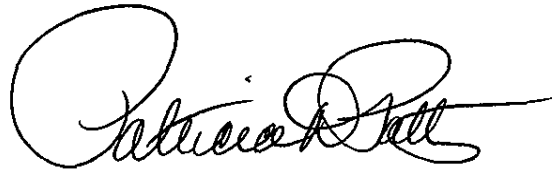
Patricia A Patten
Examiner
Art Unit 1654

Application/Control Number: 09/997,588

Page 15

Art Unit: 1654

12/11/03

A handwritten signature in black ink, appearing to read 'Patricia Patten', with a large, stylized initial 'P' and a long horizontal flourish extending to the right.

PATRICIA PATTEN
PATENT EXAMINER